REMARKS

Status of the Claims

Claims 1-31 are pending. Claims 12-14 are under examination. Claims 1-11 and 15-24 are withdrawn as directed to a non-elected invention. Claims 12-14 are amended. Support for the amendments is found throughout the specification as originally filed, including, *e.g.*, on pages 25-27. The claims are amended without prejudice or disclaimer. Claims 25-31 are new. Support for new claims 25-31 is described herein below. Reconsideration is respectfully requested.

Objection to the Specification

The title of the present application is objected to as allegedly non-descriptive. The title is amended to specify, "METHODS FOR IDENTIFYING AGENTS FOR PREVENTING OR TREATING PROLIFERATIVE DISEASES, AND FOR INHIBITING EXTRACELLULAR MATRIX OR α1 TYPE IV COLLAGEN." Applicants submit that the present title is descriptive of the claimed invention and the objection is overcome. Accordingly, Applicants respectfully request withdrawal of the objection.

Issues Under 35 U.S.C. § 101

Claims 12-14 are rejected under 35 U.S.C. § 101 because the invention as claimed is allegedly directed to non-statutory subject matter. Specifically, the Examiner states that the single "judging" step is a mental process, which is not subject to patent protection, *see* Office Action, page 4.

Independent claims 12-14, as amended, do not include a "judging" step. As amended, the claims describe active steps for performing the claimed methods. Specifically, claim 12, as amended, is directed to a method of identifying an agent effective in preventing and/or treating a proliferative disease causing sclerosis, comprising contacting a test agent with a biological sample; determining the level of expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1 and phosphorylated Smad1 in the

biological sample in comparison to the level of expression of the substance in a control sample, wherein a decrease in expression of STAT3, phosphorylated STAT3, Smad1 or phosphorylated Smad1 in comparison to the expression level of the substance in the control sample indicates the agent is effective in the prevention and/or treatment of proliferative diseases causing sclerosis.

As amended, claim 13 is directed to a method of identifying an agent effective in inhibiting the increase of extracellular matrix, comprising contacting a test agent with a biological sample; determining the level of expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1 and phosphorylated Smad1 in the biological sample in comparison to the level of expression of the substance in a control sample, wherein a decrease in expression of STAT3, phosphorylated STAT3, Smad1 or phosphorylated Smad1 in comparison to the expression level of the substance in the control sample indicates the agent is effective in inhibiting the increase of extracellular matrix.

Claim 14 is directed to a method of identifying substances effective in inhibiting the expression of α1 type IV collagen, comprising contacting a test agent with a biological sample; determining the level of expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1 and phosphorylated Smad1 in the biological sample in comparison to the level of expression of the substance in a control sample, wherein a decrease in expression of STAT3, phosphorylated STAT3, Smad1 or phosphorylated Smad1 in comparison to the expression level of the substance in the control sample indicates the agent is effective in inhibiting the expression of α1 type IV collagen.

Based at least upon the foregoing amendments, Applicants submit that claims 12-14 are directed to patentable subject matter. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 101.

Issues Under 35 U.S.C. § 102(b)

Claims 12-14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,013,522 to Monia, ("Monia"). Specifically, the Examiner states that the elements of preventing and/or treating proliferative diseases causing sclerosis, (specified in claim 12), inhibiting the increase of intracellular matrix (specified in claim 13), and inhibiting the

expression of α type IV collagen (specified in claim 14) are not given patentable weight because the body of the claim does not depend on the preamble for completeness, *see* Office Action, pages 4-5, bridging paragraph. Accordingly, the Examiner contends that Monia, which discloses determining whether or not a test substance inhibits the expression of Smad1, anticipates the instant claims, *see* Office Action, pages 4-5.

Although Applicants do not agree that the preambles of the claims are properly excluded from the Examiner's consideration, in order to expedite prosecution, the claims are amended to incorporate the preamble elements into the body of the claims. As amended, independent claims 12-14 specify elements that are not disclosed in Monia. In particular, Monia fails to describe determining whether or not an agent is effective in 1) the prevention or treatment of a proliferative disease causing sclerosis, as specified in independent claim 12; 2) inhibiting the increase of extracellular matrix, as specified in independent claim 13; 3) and inhibiting the expression of α1 type IV collagen, as specified in independent claim 14. Accordingly, the rejection is overcome and Applicants respectfully request withdrawal of the rejection.

Issues Under 35 U.S.C. § 112, Second Paragraph

Claims 12-14 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Specifically, the Examiner asserts that there is a disconnect between the preambles and the method steps specified in the pending claims. Accordingly, the Examiner states that the claims are unclear to a skilled artisan. As discussed above, claims 12-15 are amended to incorporate the elements of the preamble into the body of the claims. At least as amended, the claims are not unclear to a skilled artisan. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Additional Claims

As noted above, new claims 25-31 are submitted herewith. New claim 25 specifies that the biological sample is selected from renal tissue sections, blood, sera, or urine. Support for these elements is found, *e.g.*, on page 17, paragraph 6, in the originally filed application.

New claim 26 specifies that the biological sample is selected from mesangial cells. Support for these elements is found, *e.g.*, on page 26, paragraph 1 in the originally filed application.

New claim 27 specifies that the level of expression is measured at the nucleic acid level or the protein level. Support for these elements is found, *e.g.*, on page 13, paragraph 3, in the originally filed application.

New claim 28 specifies that the proliferative disease causing sclerosis is a renal disease, which damages glomeruli. Support for this element is found, *e.g.*, on page 17, paragraph 1, in the originally filed application.

New claim 29 specifies that the proliferative disease causing sclerosis is selected from diabetic nephropathy, chronic glomerulonephritis, membranous proliferative glomerulonephritis, focal glomerulosesclerosis, light chain disease, cryoglobulinemic nephritis, HIV-associated nephritis, purpuric nephritis, hepatic fibrosis, and arteriosclerosis. Support for these elements is found, *e.g.*, on page 17, paragraph 1, in the originally filed application.

New claim 30 specifies that the level of expression of phosphorylated STAT3, Smad1 or phosphorylated Smad1 at the nucleic acid level is measured using primer pairs selected from SEQ ID NOS. 21 and 22, or SEQ ID NOS. 5 and 6. Support for these elements is found, *e.g.*, on page 18, paragraph 4, in the originally filed application.

New claim 31 specifies that the level of expression of phosphorylated STAT3, Smad1 or phosphorylated Smad1 at the protein level is measured by Western Blotting, ELISA or immunohistochemical analysis. Support for these elements is found, *e.g.*, on page 19, paragraph 2 in the originally filed application.

CONCLUSION

In view of the above Amendment and Remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Linda T. Parker, Reg. No. 46,046, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: FEB 17 2009

Respectfully submitted,

By _____
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

GMM/LTP/bpr